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14. ABSTRACT Active surveillance (AS) is recommended for patients with low-risk prostate cancer to prevent overtreatment and maintain sexual and urinary functioning. However, approximately 90% of AS-eligible patients opt for curative treatment and 25-50% discontinue AS within 2-5 years without clinical evidence of cancer progression. Research is necessary to examine barriers and facilitators of informed decision-making and adherence to AS. We have conducted focus groups and personal interviews with patients (N = 32 patients) and care providers (N = 3) to examine barriers and facilitators of AS decisions and adherence. Factors that influence patients' decisions to opt for AS include trust in the physician's expertise, good intentions, and skills in detecting cancer progression in a timely manner, and avoidance of sexual and urinary deterioration associated with curative treatment. The partner's approval of AS played a significant role in the decision to opt for AS. Patient-provider communication and worries about cancer progression are major determinant factors of patients' AS decisions.					
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Introduction

To date, most newly diagnosed prostate cancers (PC) are low grade and low risk tumors that are confined to the prostate.¹ Active surveillance is a safe, evidence-based strategy to manage men with low-risk PC to prevent “overtreatment” and a decrease in quality of life associated with active treatment.² It involves close monitoring of the tumor with the intent to intervene with curative treatment (e.g., surgery) if disease progression is evident. In spite of the benefits of active surveillance, 90% of eligible patients opt for curative treatment.³ Furthermore, 25% of patients discontinue the active surveillance protocol within the first 2 years, and 50% do so within 5 years without evidence of cancer progression.⁴ Emotional distress related to the feeling of “doing nothing” while the cancer may be worsening, and changes in a patient’s treatment-related preferences and values are reported as the leading factors behind discontinuing active surveillance.⁵ Therefore, an intervention is urgently needed to address these issues. We propose to adopt for men on active surveillance an efficacious, symptom management intervention [Prostate Cancer Patient Education Program; PC^{PEP}], and assess its feasibility and acceptability.⁶ The PC^{PEP} was originally developed and tested for low-health literacy patients treated for early stage PC. It involves the provision of tailored modules and coaching using telehealth methods to reduce distress levels, enhance symptom management (e.g., urinary incontinence and impotence), and address unmet informational and supportive care needs during follow-up care. Prior studies found that the PC^{PEP} improved symptom management and self-efficacy beliefs among PC patients with low-health literacy.

As part of this adoption process (Phase 1), we will refine the *CPI-Prostate* modules and develop an Electronic Health Record (EHR)-based care plan for the patient and care provider. The *CPI-Prostate* program will consist of 4 modules: (1) enhanced education on active surveillance and follow-up care; (2) a tailored care plan for the patient and the provider delivered in a paper- and EHR-format; (3) a one-on-one, navigator-led session with the patient to discuss the care plan, and assess and address psychological distress and unmet needs; and (4) four navigator-led calls to continue the assessment of distress and needs, and to discuss updates to the care plan. We will conduct eight focus groups with 30 PC patients and 10 stakeholders to: (a) examine the barriers and facilitators of adherence to active surveillance, (b) explore patients’ unmet needs, and (c) inform the adoption process of the intervention modules, and the content and function of the EHR-based care plan. We will conduct usability testing to examine the utility of the penultimate version of the EHR-based care plan among 10 patients and stakeholders (50% PC patients) following NIH guidelines.

During the pilot feasibility and acceptability study (Phase 2), patients (N = 80) who are currently on active surveillance protocol will attend a 1-hour session with the navigator, followed by 4 navigator-led, follow-up calls. Outcome measures will be assessed at baseline (before the session), and at 1, 3, 6, and 12 months thereafter. The primary outcome will be the feasibility and acceptability of the intervention and adherence to active surveillance. Secondary outcomes are psychological distress, unmet needs, decisional regret, uncertainty, fear of cancer progression, quality of life, and satisfaction with care and communication. We hypothesize that the *CPI-Prostate* will be highly acceptable and feasible. Although the study is not designed to test for efficacy, we also hypothesize that patients who participate in the *CPI-Prostate* will report adherence to active surveillance, a significant decline in distress, unmet needs, and regret, and a significant improvement in quality of life and satisfaction with care and with communication from baseline to the 12-month assessment. These data will be used to power a future efficacy trial. Qualitative and quantitative statistical analyses will be used to examine the focus group input, the usability, feasibility, and acceptability testing, and changes in study outcomes (i.e., adherence, distress, fear, needs, quality of life, regret, and satisfaction) from the baseline (before the session) to 12 months after baseline.

This proposed research is innovative as it is the first time that a psychosocial and educational intervention will be used to increase adherence among PC patients on active surveillance. The use of EHR to convey and share follow-up care plans is also novel. The proposed research has high impact potential because it addresses an important problem in the care planning and symptom management of PC patients. It further has the potential to impact patients’ quality of life as well as satisfaction with care and communication with providers. The potential for integration and dissemination in the clinic by existing patient navigation staff is high.

Keywords: Active surveillance, localized prostate cancer, treatment decision making, sexual and urinary function, unmet informational and supportive care needs, quality of life, adherence to active surveillance

Accomplishments

The major study goals are:

1. To adopt a successful, symptom management intervention (PC^{PEP}) for prostate cancer patients on active surveillance (Study Specific Aim 1). As part of the adoption process, we will: (Aim 1a) develop an Electronic Health Record-based care plan for the patient and the care provider; (Aim 1b) conduct focus groups and personal interviews with patients and stakeholders to examine the barriers and facilitators of offering, acceptance of, and adherence to active surveillance, and unmet needs; inform the refinement of the prostate cancer educational modules (e.g., educational pamphlets and the Navigator session and follow-up calls); and augment the content and function of the care plan; and (Aim 1c) conduct usability testing to establish the usability of the care plan software.
2. To evaluate the acceptability and feasibility of the program with prostate cancer patients on active surveillance in a small pilot study (Study Specific Aim 2).

What we accomplished of these goals during the study period: September 2016-September 2017

Phase 2: Feasibility and Acceptability Assessment

We are still in the midst of completing phase 2 of this DoD-funded study. As of **October 24th 2017**, a total of 67 out of the intended 80 (or more) active surveillance patients subjects formally consented to participate in this phase, which involves 4 questionnaires (baseline, 3-month, 6-month, and 12 month) and 4 navigator-led phone sessions (one 1-hour initial phone session at baseline, and then 3 additional follow-up calls at 2 months, 4 months, and 12 months). Of these 67 consented patients, 27 patients have completed and returned their baseline surveys. Of these patients, 11 have completed the first 1-hour session and are scheduled for follow-ups. Two participants have formally left the study; one expressed regret due to other affairs in his life occupying too much of his time, while another simply cited loss of interest. Two other individuals have been impossible to contact since their recruitment, which we have since deemed attrition without explanation. 12 people in total declined to participate altogether, typically citing reasons such as lack of time and interest. Research Coordinator Sarah Goodman is the one who recruits patients in person at Dr. Ashutosh Tewari's urology clinic at 625 Madison Avenue. Research coordinator Qainat Shah is the one who is now conducting the navigator sessions.

The vast majority of individuals who agreed to participate (61 out of 67 so far, or 91 percent) are Caucasian. Two (3 percent) are Hispanic, two (3 percent) are South Asian, one is Black African American, and one is Black Afro-Caribbean.

Phase II: Refinement of the patient educational materials, follow-up care plan, and the navigator session and follow-up protocol

Shortly after consenting to participate, patients are sent, along with a copy of the baseline survey and a stamped return envelope including:

- 1) An informational packet entitled "What You Need To Know About Active Surveillance of Prostate Cancer" that uses information and illustrations from the National Cancer Institute's *What You Need To Know About Prostate Cancer* (2012)
- 2) A booklet written and designed by Dr. David Latini, PhD entitled "Prostate Cancer Patient Education Project (PC^{PEP})"
- 3) A copy of the National Comprehensive Cancer Network's Distress Management Thermometer
- 4) A resource guide of other services at Mount Sinai Health System and elsewhere in the New York City area that may be of interest to the patient, categorized by the items on the NCCN Distress Thermometer
- 5) The follow-up *Care Planning Worksheet* designed by Dr. Nihal Mohamed, PhD

6) A letter welcoming the participant to the study, explaining the contents of the packet, and thanking them for their time

As mentioned in the prior annual report, the intervention modules have already been developed. Indeed, the patient navigator's session draws upon the National Comprehensive Cancer Network's Distress Management Thermometer, as well as the resource guide of other services at Mount Sinai Health System and elsewhere in the New York City area that may be of interest to the patient, categorized by the items on the NCCN Distress Thermometer. Furthermore, our team recently acquired permission from the Mount Sinai IRB to modify this study such that we can also recruit caregivers of participants. While consenting the patient, the CRC (Sarah Goodman) asks whether or not he grants permission to contact his caregiver, who is most often an intimate partner (but can also be a family member.) This is an additional, newly-developed arm of the study that will investigate caretakers' unmet needs during their patients' time on active surveillance. Should the patient initially consent to this, the team will then contact the caregiver in question to obtain his or her consent. Should a caregiver / partner accompany the patient to his appointment at the midtown Sinai clinic, they can be asked simultaneously. Partners who decline will not be contacted further, while those who express interest will sign a caretaker-tailored consent form, complete a series of caretaker-tailored questionnaires (one baseline and 3 follow-up; i.e. at the same time increments as the patients' questionnaire), and partake in an initial navigator-led phone session with four follow-up calls, similar to that of the patients. Caregivers' initial willingness to participate or decision to terminate their involvement will not affect their patient partners' participation (and vice versa), nor will either's participation in the study affect present or future care at the Mount Sinai Health System in any foreseeable way. Therefore, recruitment of the caregivers will start soon and follow the same intervention and outcome assessment procedures we are using for the patients. Including the caregivers in this study will provide further information about the feasibility and helpfulness of the intervention for both patients and their family caregivers.

Opportunities for training and professional development the project has provided

Phase II of this project has provided members of our team with several important opportunities for professional growth and development. It has enabled the study PI (Mohamed) and her research team to understand the challenges and difficulties patients with prostate cancer face when making decisions about active surveillance. The project also provided the opportunity to collect additional qualitative data via participants' navigator sessions on possible unmet informational and supportive care needs during management of active surveillance, and encouraged the inclusion of caregivers, hence the aforementioned IRB-approved modification

Furthermore, inclusion and training of the new clinical research coordinator Qainat Shah has allowed her to practice her one-on-one, formal interaction with patients as she conducts the navigator sessions. CRC Sarah Goodman has been able to develop her managerial and administrative skills when it comes to scheduling, documenting, and organizing pertinent information regarding recruitment, interview times, and due dates for follow-up activities. Both Ms. Shah and Ms. Goodman completed training in patient navigation, and will gain additional experience with data analysis (particularly that of longitudinal data) and use of transcription software. Team members have increased their general knowledge base of active surveillance, as well as common AS patient needs and how to appropriately discuss them with patients. Phase II results, when they are available, will inform a future, large-scale randomized control trial that will examine the effectiveness of this planned intervention (when the final product has been developed). These endeavors will further enhance Dr. Mohamed's already remarkable and laudable progress in the research of prostate cancer and other urological (and subsequent psychosocial) afflictions.

Study results disseminated to communities of interest

Phase II endeavors are incomplete, and thus have yet to be shared with the general research community. Information regarding the dissemination of results will be explained in future reports.

Plan for the next reporting period to accomplish the study goals

The next reporting period will focus on continuing the evaluation of the acceptability and feasibility of the program with prostate cancer patients on active surveillance in a small pilot study (Study Specific Aim 2). We plan to recruit 80 prostate cancer patients and 30 caregivers during this 24-month period and explore the acceptability and feasibility of the planned intervention described above.

Impact

The impact on the development of the principal discipline(s) of the project

Phase I focus groups and interviews results have been used to inform revisions and finalization of the intervention components and content. Patients reported unmet informational needs guided the development of the patient brochure (attached) and the revision of the follow-up care plan (attached). The navigator session and follow-up calls have been designed to address major issues raised by patients during the focus groups and interviews (e.g., anxiety of having cancer, fear of cancer progression and future worries).

The impact on other disciplines

Although there is nothing to report at this time, a significant impact of the intervention on other disciplines including patient psychological support during active surveillance management is expected. Phase II results will provide evidence for such impact.

The impact on technology transfer

Although there is nothing to report at this time, Phase II will provide evidence of the impact of an intervention

The impact on society beyond science and technology

Phase II results are anticipated to increase general knowledge about challenges and difficulties patients face during the treatment decision making and active surveillance management. Increased public awareness of issues that influence patients' decisions about active surveillance may lead to improved patient-physician communication about active surveillance and, thus, increased uptake of active surveillance among patients. This will reduce patient burden and cost of care and prevent unnecessary reduction of quality of life associated with curative treatment.

Changes/problems

During the first and second quarters of this awarded study, we experienced some delay in hiring the study personnel (Research Assistant [15%], Research Coordinator [20%]) because of the limited funding allocated to these two positions. However, we have managed to resolve this issue. Ms. Taleen Bolbolian, a former research coordinator, left Mount Sinai on 1/7/2016 for a higher paying job. Ms. Sarah Goodman replaced Taleen Bolbolian several months later and inherited Bolbolian's responsibilities. This hiring delay led to an precipitous delay in starting Phase II (the feasibility study). However, we have increased patient recruitment for Phase II as we recruit from 2 physicians (Dr. Ashutosh Tewari and Dr. Reza Mehrazin) at Mount Sinai. Our most updated patient medical data revealed that we have currently over 250 prostate cancer patients on active surveillance, and our medical data show that more newly diagnosed patients at Mount Sinai now are opting for active surveillance compared to previous years. Thus, recruiting 80 patients during the remaining study period (2-year) will be feasible. Additional resources for patient recruitment are available via Mount Sinai affiliated hospitals including Mount Sinai-Queens and Mount Sinai-Beth Israel.

Products

Phase II Product:

Phase II products include the following:

- 1) A baseline survey assessing psychosocial functioning and potentially unmet needs while on AS

- 2) A follow-up survey of the same nature (same questions, with additional components asking participants to evaluate the quality and helpfulness of the navigator sessions)
- 3) An informational packet entitled “What You Need To Know About Active Surveillance of Prostate Cancer” that uses information and illustrations from the National Cancer Institute’s *What You Need To Know About Prostate Cancer* (2012)
- 4) A booklet written and designed by Dr. David Latini, PhD entitled “Prostate Cancer Patient Education Project (PC^{PEP})”
- 5) A copy of the National Comprehensive Cancer Network’s Distress Management Thermometer
- 6) A resource guide of other services at Mount Sinai Health System and elsewhere in the New York City area that may be of interest to the patient, categorized by the items on the NCCN Distress Thermometer
- 7) The follow-up *Care Planning Worksheet* designed by Dr. Nihal Mohamed, PhD
- 8) A letter welcoming the participant to the study, explaining the contents of the packet, and thanking them for their time
- 9) A routinely updated database documenting in great detail those who are participating in the study, their demographics, dates their surveys were mailed, and dates of their navigator sessions (a secondary excel sheet documents those who have declined and their reasons for doing so)
- 10) A routinely updated database of those patients who are on active surveillance (and are therefore eligible for recruitment). This database is cross-referenced with those scheduled for appointments on given days to see who is eligible to be approached and recruited at the clinic
- 11) A folder including updated literature on AS and PC
- 12) An outline and guide for the navigator session

Phase II Product:

We have completed the design, refinement, and finalization of the feasibility study materials. The following materials are currently readily available for usability testing (care plan) and feasibility testing.

- Patient pamphlet
- Patient Follow-up Care Plan
- Navigator 1-hour session
- Navigator follow-up calls
- Study finalized outcome measures (pre- and post-intervention assessment; see Appendix E).

Participants and other collaborating organizations

Dr. Nihal Mohamed

Project Role: Principal Investigator

Researcher Identifier: NIHALM (eRA Commons)

Nearest person month worked: 80 hours

Contribution to Project: Dr. Mohamed designed the study materials described above, worked with the ISMMS and DOD IRB to approve the study methodology and study materials, and met with the research team to review and edit protocols and regulatory documents.

Dr. Heather Goltz

Project Role: Co-Investigator

Researcher Identifier: hhhonore (eRA Commons), 0000-0002-2875-7764 (ORCID ID)

Nearest person month worked: 50 hours

Contribution to Project: Dr. Goltz met with the research team to review and edit protocols and regulatory documents, creating a study flyer, and reviewing and editing the focus group and interview guides. Dr. Goltz also created the first draft of the outlines of the navigator session.

Dr. David Latini

Project Role: Collaborator

Nearest person month worked: 3 hours

Contribution to Project: Dr. Latini met with the research team to review and edit protocols and regulatory documents, creating a study flyer, and reviewing and editing the focus group and interview guides and assisted with the intervention development and selection of study outcome measures.

Dr. Joseph Kannry

Project Role: Co-Investigator

Nearest person month worked: 3 hour

Contribution to Project: Dr. Kannry met with the research team to discuss the care plan and will schedule frequent meetings with the PI (Mohamed) and his research team to discuss progress in developing the plan and the software.

Dr. Ash Tewari

Project Role: Co-Investigator

Nearest person month worked: 3 hour

Contribution to Project: Dr. Tewari met with the research team to discuss the study progress and will schedule frequent meetings with the PI (Mohamed) to discuss study update. Dr. Tewari also assisted with patient recruitment for Phase 1 and 2.

Dr. Reza Mehrazin

Project Role: Co-Investigator

Nearest person month worked: 3 hour

Contribution to Project: Dr. Mehrazin met with the research team to discuss the study progress and will schedule frequent meetings with the PI (Mohamed) to discuss study update. Dr. Mehrazin also assisted with patient recruitment for Phase 1 and 2.

Ms. Sarah Goodman

Project Role: Clinical Research Coordinator

Nearest person month worked: 80 hours

Contribution to Project: Ms. Goodman assisted with patient recruitment and scheduling of the focus groups and patient interviews. She has worked closely with Dr. Mohamed to update the literature on Active Surveillance, definitions, medical protocol, and the revision of the care plan. She has also participated in the online navigation training.

Ms. Qainat Shah

Project Role: Clinical Research Coordinator and Patient Navigator

Nearest person month worked: 50 hours

Contribution to Project: Ms. Shah also assisted with patient recruitment, and is now primarily responsible for conducting the patient navigator interview sessions. She has worked closely with Dr. Mohamed to update the literature on Active Surveillance, definitions, medical protocol, and the revision of the care plan. She has also participated in the online navigation training.

Special reporting requirements

On July 11th, 2017, Sarah Goodman met with Laura Leone, LMSW of the Institute for Family Health in Harlem, NYC for additional training on interacting effectively with patients during navigator sessions. Laura Leone also came to the Mount Sinai premises on August 21st, 2017 to conduct a training session in conflict resolution with several Sinai Urology department employees, including Dr. Mohamed, Ms. Goodman, and Ms. Shah. A one-on-one training session between Ms. Leone and Ms. Shah will be scheduled in the near future.

We have also presented our focus group findings at the Prostate Cancer International Symposium at Mount Sinai in September 6-9, 2017.

We also did receive 2 more awards; DoD Disparity award examining racial, cultural, and dyadic influences on patients' decisions about active surveillance for prostate cancer [PC160194] and the National Institute for Nursing Research (NINR).